External fixator for osteosynthesis or bone gap manipulation

The invention relates to an external fixator for osteosynthesis or bone gap manipulation, comprising an external retaining member and connecting elements with retaining ends held in the retaining member and with contact ends to be placed on the bone for connecting the retaining member to the bone or to bone parts. The invention relates in particular to an external fixator for closing a dislocated bone and the parts thereof, for example a sternum which has been cut through.

Definitions

- External is to be understood as meaning that substantial parts of the fixator, in the specific case the retaining member, comes to rest outside a patient's body in the application. Parts of the fixator, in particular the connecting elements, naturally engage the bone, but, according to the invention, without in principle penetrating into it. In addition to the connecting elements, it is also possible, in the context of the invention, to use wires, ropes or cables which may optionally penetrate the bone – as known per se.
- Connecting elements are to be understood generally in the context of the invention. They are – generally elongated – components which come to rest between the retaining member and the bone and mutually support the two parts.
- Dislocated bone is to be understood as meaning all bones which have been divided into bone parts – by fracture or intervention – but in particular bones which have been split in their longitudinal direction, such as, for example, a sternum after a heart operation.

Such external fixators are known:

for example, IL-A-122418/2 of 2.12.1997 describes such an external fixator

which consists of an external rod as a retaining member, to which threaded rods are screwed as connecting elements. The threaded rods carry, on their end projecting from the retaining member, the contact end, two screwable plates each, one of which comes to rest below the sternum and one above the sternum. In the position of use, a sternum is thus connected to the plates in the manner of a sandwich. Consequently, the relative distance between sternum and retaining member is variable. The threaded rods lie laterally next to the sternum. By moving the threaded rods on the retaining member, more or less pressure can be applied to the sternum from the lateral to the medial direction. A reduction of the pressure to a negative force is not possible since the plates and threaded rods would migrate away from the sternum if the threaded rods were moved laterally (cf. Fig. 6 of the IL document).

In this known design, another disadvantageous effect occurs when the pressure is increased: the threaded rods, which in fact rest laterally against the sternum, bend in the lateral direction so that there is a tendency for the lower plate to swivel outwards and the upper plate inwards (in a medial direction and downwards). This leads to an increase in the pressure on the upper region of the gap in the sternum and to a reduction of the pressure in the lower region of the gap. This can lead to undesired deformations of the sternum.

Furthermore, it is regarded as being disadvantageous if the lower plate comes to rest over a relatively large area below the sternum, i.e. in a critical region close to the heart. This is undesirable from the point of view of heart surgery and cardiology.

On the other hand, this known design permits the removal of the fixator after healing of the bone gap without a further operation, by virtue of the fact that the plates become loose and the threaded rods can then be extracted in an upward direction. Even when the plates have not yet become loose, the

threaded rods can be removed from the plates by turning.

Compared with other known methods, this is advantageous since in this method parts of the fixator remain in the patient, in particular wires or plates.

Systems which remain in the patient have been published in the following documents. As a rule they relate to the old tradition of winding wires around a sternum and twisting these wires: WO88/06022; US5318566; US4583541; US6217580; US6540769 and DE-U-20309158.

Other conventional external fixators which operate with bone screws as connecting elements have the disadvantage that it is necessary to drill into the bone, which is problematic in the case of porous and thin bones. In addition, precisely in the case of a sternum, there is a high degree of uncertainty in the case of drilling since medistinal perforation of the sternum should be avoided. Moreover, in the case of improper mounting of a bone screw, the latter can also penetrate into the space below the sternum.

The object of the invention is therefore the development of an osteosynthetic connection system which permits simple, rapid and safe handling in particular for heart surgeons in the region of the sternum. Owing to the localization, the system is subject to intermittent very high forces due to the concomitant thoracic movement in the case of strong inspiration or exspiration and also in the case of attacks of coughing. A further known problem is the anchoring of the system. The sternum is a flat bone which may additionally exhibit osteoporotic changes. The anchoring may be torn out, and there is also the danger of pleural/pericardial injury due to bone perforation. Because little subcutaneous tissue is present in the region of the sternum, wound healing should be critically assessed. For this reason, as far as possible any further burden on the soft tissue should be avoided by means of an external fixator. Materials which are well tolerated by tissue should be used.

The external fixator should permit the advantage of individual friction adjustment. According to the invention, there should be an initial compression at the bone gap, which can be changed into a tension at the bone gap from a certain period onwards for improved bone healing. This is not possible in the case of all conventional methods, with the exception of a conventional external fixator with bone screws.

However, external systems with bone screws often cannot be used precisely in the case of a sternum.

The system must be worn over a period of at least two months. In contrast to the internally worn wires of other closure systems, this means a certain annoyance for the patient, which however subsequently vanishes whereas the internal systems can be removed again only by means of a further operation.

The object should be to provide a device which is scarcely noticed by the patient and gives the latter a safe feeling. The basic requirements are a flat design, low weight and simple hygienic handling.

This object is achieved by the design according to the invention and its special embodiments:

By an external fixator for osteosynthesis or bone gap manipulation, which is equipped, in a manner known per se, with an external retaining member and connecting elements with retaining ends held in the retaining member and with contact ends to be placed on the bone for connecting the retaining member to the bone or to bone parts, in contrast to the known fixator the connecting elements or the contact ends thereof not being screws or the like, so that they are therefore not screwed into the bone, which is a major advantage particularly in the case of small and thin bones and in the case of

porous bones, it being possible instead for the contact ends to be supported only on the surface of the bone and to be formed in such a way that the contact ends or that the connecting elements can exert a lateral clamping/compression pressure on the bones or the bone parts. In the case of a sternum, for example, this would be a lateral pressure in the direction of the sagittal plane.

Furthermore, according to the invention, a control element supported in the retaining member is coordinated with each connecting element in the retaining member, by means of which control element the clamping pressure can be varied.

As a result of this novel design, it is therefore possible for the first time, without having to drill into the bone parts, to manipulate the gap between the bones in a controlled manner, i.e. to increase or to decrease it, or to apply, to increase or to reduce a closing pressure on the gap.
In order also to be able to keep the contact ends pressed against the bones from the distal direction, various possibilities – depending on the type of bone – are conceivable in the context of the invention. Thus, a fixator according to the invention may be kept pressed against the bones by a suitable bandage.

According to a particular development of the invention, however, such contact pressure is not necessary at all since, in the case of this development, the contact ends are formed in a spoon-like manner so that they can at least partly surround a bone, for example a sternum, from the lateral direction. The extent of this surrounding depends on the type of bone and on its formation. What is decisive in the case of the spoon-like formation is that, as a result of the partial surrounding, the connecting elements and hence the retaining member are held by themselves on the bone.

It is of course advantageous if the contact ends are profiled so that they are

held without slipping when used on the bone surface. If in addition at least one counter-holder connectable or connected to the retaining member is provided, which, in the inserted state, applies pressure to the bone in the distal direction relative to the retaining member, external bandages and also spoon-like formations can be dispensed with because the counter-holder then ensures the connection between bone and connecting elements. In this embodiment (with surrounding alone), it is however scarcely possible to exert a negative pressure on the bone gap. Variation of the pressure from low to high is however readily possible.

The counter-holder preferably comprises at least one flexible, wire- or cable-like loop which can be wrapped around the surface of the bone and can be fixed indirectly or directly to the retaining member. Thus, a surgical material known per se, namely a wire or a cable, is used, but in contrast to the prior art in that it performs the function not only of connecting the bone parts but also of keeping the external fixator pressed against the bone.

A possible development with such loops is present, for example, when the loop can be wrapped along the spoon-like formations and around the surface of the bone. This results in a bone-protecting path since it is precisely in the edge region of bones, in particular flat bones, that the localized load due to wires or cables is particularly great. On the other hand, there are certainly applications in which such spoon-like surrounding systems tend to be troublesome; for example, particularly in the case of the breast bone (sternum), it is not desirable to have hard inflexible parts, since it is there directly underneath that the heart beats with possibly bypasses or the like freshly provided by surgery, which should be irritated as little as possible.

For this reason, variants without surrounding systems are preferred in the context of the invention.

In such or other variants, the connecting elements are, for example,

U-shaped or I-shaped in section, in particular such that the loop is led or can be led in a U or in an I, and that, in the assembled state, each loop wraps around one connecting element each on a bone part and one connecting element each on another bone part and the two bone parts and can fix them on the retaining member. In a preferred variant, the connecting elements are hollow, in particular tubular, and can cooperate with the loop or the loops so that, in the assembled state, each loop winds through one connecting element each on a bone part and another connecting element each on another bone part and wraps around both bone parts and can be fixed on the retaining member.

The design of that end of these connecting elements which faces the bone (contact end) is such that the bone parts can be subjected to pressure from the lateral direction as well as in the lateral direction thereby so that any desired bone gap manipulation is possible.

This design was successfully tested on a prototype. It is distinguished by a compact appearance and protects the loop from the environment.

In a further development of this variant, the tubular connecting element has at least one lateral orifice for the entrance or emergence of the loop, a distance away from the contact end. This design is advantageous because in this way the contact end can rest against the bone undisturbed by the cable. In fact, the cable leaves the connecting part above the contact end. However, other conceivable variants are developments in which the contact end has, in its end face, a slot which receives the loop or the cable when it leaves the tube.

Since the fixator according to the invention tends to be bulky, it might reduce the X-ray vision of body parts underneath, for example heart and lung. In order to prevent this, a particular development ensures that the connecting elements and/or the retaining member are composed of X-ray-transparent

material which consists in particular of light metal or of a light metal alloy or of carbon or of a carbon-reinforced material. It is also advantageous if the cable and the loops consist of carbon, since this material is well tolerated and is inert to many body substances and therefore does not intergrow with a wound.

Particular developments of the contact end are present if the contact end is bevelled in the manner of a wedge or rounded along a curve and preferably toothed. Depending on requirements, optimum support can thus be chosen. It is particularly preferable if the connecting elements can be chosen from a group of different embodiments and can be inserted into a retaining member so that the ideal connecting element can be chosen for the specific point of use.

Clamping screws – preferably locking screws – preferably serve for fastening the cable in or on the retaining member.

Locking screws are clamping screws which have a built-in latch mechanism or the like, so that clamping is possible but release of the clamp is possible only by special measures (e.g. latch release). As a result of this preferred development, a clamped cable or a clamped loop can thus be retensioned in a simple manner turn by turn without having to fear an accidental decline in the tension.

A particular universality of a design according to the invention is achieved thereby if the two connecting elements coordinated in each case with one another in a parallel transverse plane or in a normal plane relative to the retaining member are displaceably or preferably pivotably mounted therein transversely to the longitudinal dimension thereof, this universality increasing even further if the connecting elements are additionally preferably displaceable or pivotable in one plane each parallel to the sagittal plane or in one plane each normal to the retaining member, along the longitudinal

dimension thereof. Thus, each connecting element can be adjusted in two planes, and the adjustability in the transverse planes serves for tensioning the loops and at the same time for subjecting the bone parts to lateral displacement loads. This design according to the invention permits gentle, nondestructive osteosynthesis in an optimum manner, it being possible to remove the external fixator completely when the osteosynthesis is complete, without exogenous materials remaining in the body. The loops can be pulled out in the proximal direction in the same way as sutures, as can the connecting elements. The retaining member itself is always outside the body.

Since the cable rests against the bone along a line, there is no localized load, as is otherwise the case with screwed systems. Since the cable is flexible or elastic, this clamping method corresponds fairly well to the bone physiology. In particular, there is the advantage that the bone is kept optimally pressed against the connecting elements and the latter can therefore display their bone gap manipulation effect – which is adjustable by the control elements. Actuation of the control elements therefore not only leads to an adjustment of the control elements but simultaneously also affects the tension of the loop, thus permitting easy operation.

Of course, the invention also comprises variants in which the loop tension is adjustable independently of the connecting element adjustment. The invention also comprises attachments in which, in the assembled state, the loops are led through thin holes in the bone instead of being led laterally past the bone. This may be advantageous where it is desired to secure the position of the loops in the bone to prevent slipping.

A control element according to the invention comprises, for example, a screw or a threaded pin, which screw or which threaded pin comes into contact indirectly or directly from the lateral direction with one connecting element each and thus defines its pivot or displacement position relative to the retaining member.

Of course, restoring elements, such as springs or springy support parts or the like, can also be provided for such connecting elements, in order to be able to operate a fixator according to the invention in as defined a manner as possible during surgery.

In connection with the invention, a zip system for skin closure can preferably be provided when the fixator has been inserted, said system being perforated in the region of the connecting elements for passage of the latter.

For improved hygiene, it is possible to ensure that the connecting elements comprise an elastic closure which – in the case of tubular connecting elements – closes its cavity but can be passed through the loop, the closure preferably comprising a sterile or biocidal material, in particular wax, fabric or foam.

In combination with the closure, or independently thereof, the retaining member may comprise a cover which makes it possible to close the region of the retaining ends, for further improvement of the hygiene. This fixator is therefore a completely self-contained system without an open connection to the outside.

The loop can be fixed to the retaining member or, according to a further development of the invention, can be held in a clamping mechanism which can be released or clamped stepwise or in stages. A locking screw is preferred for this too; however, an attachment similar to a gear or in the form of a tension lock can be provided.

For example, the clamping mechanism or the fixing to the retaining member can, however, also comprise a screw nipple of the Bowden cable type.

Particularly preferred embodiments of the invention for a closure of a

sternum opened along the sagittal plane comprise – as already partly described above – the following features:

An external retaining member and connecting elements with retaining ends held in the retaining member and with contact ends to be placed on the bone, for connecting the retaining member to the bone or to bone parts, and having a counter-holder which holds the bone distally in the direction of the retaining member, the connecting elements or the contact ends thereof being screws or the like and the contact ends only being supported on the surface of the bone and being formed in such a way that they or that the connecting elements can exert a lateral clamping pressure (directed towards the sagittal plane) on the bone or the bone parts, the counter-holder comprising at least one flexible, wire-like or cable-like loop which can be wrapped around the medial and lateral surface of the bone and can be fixed indirectly or directly to the retaining member.

As already described, it is preferable in this embodiment if, in the retaining member, a control element which is supported in the retaining member and by means of which the clamping pressure of the loop can be varied is coordinated with each connecting element or each loop, and if the or each loop is supported on and/or led to at least two connecting elements each.

Further developments of the invention and variants thereof are described in the dependent Patent Claims.

Description of function

In the invention, carbon fibre cables are preferably used. These must have a certain degree of flexibility. They must on the one hand permit problem-free introduction and removal in that the cables are smooth and slide around the sternum with a certain degree of bending. On the other hand, they must have

a high degree of tensile strength.

The carbon fibre material is well tolerated by the skin, and moreover substantial intergrowths with the surrounding tissue are kept at a low level, which is important with regard to the duration for which it is worn (at least 2 months). The carbon fibre cables are positioned intercostally.

The cables pass through tubular connecting elements which are introduced transcutaneously, rest on the sternum and do not penetrate the latter.

For the implantation, incisions about 1 to 1.5 cm from the wound edge are made and are widened by means of a hollow pin. The cables, which may run in two possible ways (see below), are then led through this hollow pin and are threaded into the connecting elements or into the retaining member, which is in the form of a plate. The connecting elements with plate or retaining member are then passed through the skin, sliding on the carbon fibre cables, and pressed on the sternum, depending on the model. Owing to their preferably profiled design, they are well retained there.

The plate itself comprises a material which is not opaque to X-rays, such as, for example, plastic, hard rubber, carbon, light metal or the like.

Description of the figures

The invention is explained in more detail by way of example with reference to embodiments.

The figures are described (in the case of a plurality of figures) in relation to one another and overall. Identical reference numerals denote identical components, and reference numerals having different indices indicate functionally identical components.

Fig. 1 shows the schematic overall design with cross-loop;

Fig. 2 shows a schematic diagram of an alternative attachment with single loop;

Fig. 3 shows another situation of the attachment according to Fig. 2 and

Fig. 4 shows a skin closure system which can preferably be used with the invention.

Substantially two exemplary models of an external fixator according to the invention, having different cable paths and methods of fixing, are presented:

Fig. 1 shows an attachment with cross-loop of the loop 7a:
In the lower part, a section along the transverse plane through a patient, in particular through the sternum thereof, with inserted external fixator according to the invention, is shown, and a section along a frontal plane is shown above this, where only one loop 7a is shown, with its particular wrap-around, which in this case simultaneously exerts the control tension on connecting elements 2a and 2b and thus applies more or less pressure to a bone gap 15.

The loop 7a which is placed between one connecting element 2a each of a bone part 5a and one connecting element 2b each of the second bone part 5b is introduced basally and medially . In the assembled state, said loop therefore consists of a crossed carbon fibre cable which is threaded into the hollow connecting elements 2a and 2b, at least three and not more than, for example, four of which are used per bone part 5a or 5b. The retaining ends 3a and 3b of the connecting elements are fastened to a plate-like retaining member 1 with a stable angle, and contact ends 4a and 4b of the connecting elements 2a and 2b, respectively, are anchored in the sternum in the manner of "ski stocks" but do not penetrate into the bone 5. The carbon fibre cables

7a are individually fixed in the retaining member 1 by means of graduated screws or by means of screws or threaded pins 10.

In contrast to Fig. 1, Fig. 2 shows only one one-part diagram with a single loop of the loop 7b with an articulated system of retaining ends 3c and 3d in the retaining member 1. The articulated system is formed in such a way that the connecting elements 2c and 2d can be pretensioned not by a cross-over loop 7a but by means of control elements 6b which, with the aid of a clamping mechanism 14, make contact laterally with the connecting elements 2c and 2d. The clamping mechanism 14 is only indicated since the person skilled in the art can devise a very wide variety for this purpose, in particular those where he can subject the connecting elements not only to pressure but also to tension. Springs (restoring springs) or the like which cooperate with the clamping mechanism 14 so that the connecting elements 2 are each subjected to pressure can also be provided for this purpose. In the case of the attachment according to Fig. 2, lateral introduction of the carbon fibre cables 7b into the base of the hollow connecting elements 7c,d and fixation in the retaining member 1 by means of graduated screw 10 are effected. There is no cross-over of the cables 7b. In order to generate compressive force at the upper edge of the sternum 5a, 5b, a lateral pressure on the connecting elements 2c, 2d and hence also on the cables 7b running therein is generated by the clamping mechanism 14. This is possible by various types of techniques, three of which are mentioned by way of example:

a) Worm thread
b) Screw thrust system, fastening of the pin to the plate by means of a barrel joint
c) Screw tension system, connecting elements run in a control groove of a cam which can be rotated by means of screw force.

In the case of all techniques used, a basal one-point fixation in the oblique connecting element position is advantageous.

Fig. 2 shows the system after assembly but without strong compression.

In Fig. 3, it is evident that the connecting elements 2c and 2d were swivelled inwards under the pressure of the clamping mechanisms 14 and control elements 6b acting laterally on them, and the two bone parts 5a, 5b of the sternum are therefore compressed in the medial direction, which leads to closure of the gap 15.

The skin closure should not be effected in the customary manner by means of an intracutaneous suture. The use of a zip system 11, as shown in Fig. 4, is recommended. It can easily be applied and removed. In addition, it has the major advantage of simple opening of the zip 11 with subsequent checking of the wound without having to remove the entire fixator beforehand, if problems with wound healing should be encountered.

Summary of advantages of the preferred embodiment:

- Forces are distributed throughout the system by the plate-like retaining member 1 located about 1 to 2 cm above skin level, so that the compressive force at the base of the connecting elements 2c, 2d decreases in the direction of the sternum (at the contact ends 4c, 4d), and the risk of perforation is minimized in this manner. There is good applicability where there is osteoporosis.
- With a cover (not shown) and/or application of a tampon to the hollow connecting elements 2 (likewise not shown), a completely self-contained system results, which permits no direct access to the mediastinum for pathogens.
- No intergrowths owing to the carbon fibre material, it being possible for the connecting elements 2 as well as the retaining member 1 to be composed of carbon. Individual friction adjustment by graduated screws. Size and height flexibility through exchangeable connecting elements 2.

- Flexibility of respiration through certain elasticity in the entire system, in particular in the loops 7.
- Designable, exchangeable retaining members in the form of a plate
- Improved hygiene
- Flat design

Summary: The invention therefore relates primarily to an external fixator which has a retaining member 1 and connecting elements 2 which can be connected without screws to a bone or bone parts 5, in particular to both halves of an opened sternum, and provide possibilities for increasing or reducing the compressive stress between the two bone parts 5 or sternum halves.

In the above text, it is true that reference is made to a system for a sternum; however, the invention is not restricted thereto but rather is also available for other bones. The Patent Claims are to be interpreted in a correspondingly broad manner.

The list of reference symbols and the drawing, together with the subjects described or protected in the claims, are an integral part of the disclosure of this Application.

List of reference numerals

1 - Retaining member...

2a,b,c,d - Connecting element, U-shaped, I-shaped, tubular...

3a,b,c,d - Retaining end...

4a,b,c,d - Contact end, bevelled, formed along a curve...

5a,b - Bones, bone parts...

6a,b - Control element, in the case of Fig. 1: loop 7a

7a,b - Counter-holder, loop...

8 - Hole

9 - Normal plane

10 - Screw or threaded pin or locking screw

11 - Zip system

12 - Region of the connecting elements

13 - Closure

14 - Clamping mechanism

15 - Bone gap